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NOTICE OF ALLOWANCE AND FEE(S) DUE

32361 7590 11/07/2008

GREENBERG TRAURIG, LLP
MET LIFE BUILDING
200 PARK AVENUE
NEW YORK, NY 10166

EXAMINER

SMYTH, ANDREW P

ART UNIT

PAPER NUMBER

2881

DATE MAILED: 11/07/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,456

01/17/2007

Ernest Balestracci

84637.010702

1342

TITLE OF INVENTION: IMPROVED CONTAINERS FOR PHARMACEUTICALS, PARTICULARLY FOR USE IN RADIOISOTOPE GENERATORS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	02/09/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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32361 7590 11/07/2008

**GREENBERG TRAURIG, LLP
MET LIFE BUILDING
200 PARK AVENUE
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,456 01/17/2007 Ernest Balestracci 84637.010702 1342

TITLE OF INVENTION: IMPROVED CONTAINERS FOR PHARMACEUTICALS, PARTICULARLY FOR USE IN RADIOISOTOPE GENERATORS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 02/09/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
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SMYTH, ANDREW P 2881 250-507100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,456	01/17/2007	Ernest Balestracci	84637.010702	1342
32361	7590	11/07/2008	EXAMINER	
GREENBERG TRAURIG, LLP MET LIFE BUILDING 200 PARK AVENUE NEW YORK, NY 10166			SMYTH, ANDREW P	
			ART UNIT	PAPER NUMBER
			2881	
DATE MAILED: 11/07/2008				

Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/597,456

Examiner

ANDREW SMYTH

Applicant(s)

BALESTRACCI ET AL.

Art Unit

2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05/29/2008.
2. ☒ The allowed claim(s) is/are 1-4,6-33,38 and 39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>01/26/2007</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Response to Amendment

1. Claims 1 and 5 amended and claims 8-11, 14-15, 17-23, and 26-28 amended by examiners amendment.
2. Claims 5, 34-37 and 40-53 canceled.

Response to Arguments

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elizabeth Belden on 10/15/2008.

The application has been amended as follows:

8. (Currently Amended) The improved pharmaceutical container of claim [[7]] 1, further comprising two stoppers which form tight seals with and prevent leakage from an open top end and an open bottom end of the column, the stoppers being made of a material which is resistant to radiation; and, optionally further comprising a packing material which optionally contains a pharmaceutical agent; wherein the bottom stopper takes up substantially all of the space at the open bottom end of the column, without blocking the outlet arm, so as to reduce the amount of the dead volume at the bottom of the column.
9. (Currently Amended) The improved pharmaceutical container of claim [[7]] 1, 2 or 8, further comprising two stoppers which form tight seals with and prevent leakage from an

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open top end and an open bottom end of the column, the stoppers being made of a material which is resistant to radiation; and, optionally further comprising a packing material which optionally contains a pharmaceutical agent; wherein said stoppers are made of a material selected from the group consisting of isoprene/chlorobutyl, bromobutyl and FM 140/0.

10. (Currently Amended) The improved pharmaceutical container of claim [[7]] 1, 2 or 8, further comprising two stoppers which form tight seals with and prevent leakage from an open top end and an open bottom end of the column, the stoppers being made of a material which is resistant to radiation; and, optionally further comprising a packing material which optionally contains a pharmaceutical agent; wherein said stoppers are made of isoprene/chlorobutyl.

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11. (Currently Amended) The improved pharmaceutical container of claim ~~[[7]]~~ 1, 2 or 8, further comprising two stoppers which form tight seals with and prevent leakage from an open top end and an open bottom end of the column, the stoppers being made of a material which is resistant to radiation; and, optionally further comprising a packing material which optionally contains a pharmaceutical agent; wherein each of said stoppers comprises a top cylindrical portion and a bottom cylindrical portion, said bottom cylindrical portion having a diameter sufficient to insure a tight seal between the stopper and the cylinder interface, and said top cylindrical portion having a diameter greater than the bottom cylindrical portion.

14. (Currently Amended) The improved pharmaceutical container of claim 7 ~~8 or 12~~, further comprising a centrally located indentation at a top end of each of the stoppers ~~stopper~~.

15. (Currently Amended) The improved pharmaceutical container of claim 7 ~~8 or 12~~, wherein the stoppers are held in place by crimping a crimp seal around the stoppers to affix them to the container.

17. (Currently Amended) The improved pharmaceutical container of claim ~~45 or~~ 16, wherein the automatic crimper is a pneumatic crimper.

18. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimp seal is crimped at a pressure of about 60-140 psi.

19. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimp seal is constructed of a material which is resistant to radiation.

20. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimp seal is constructed of a material selected from the group consisting of aluminum, steel and tin.

21. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimped stopper is able to withstand a pressure of between 90 psi and 200 psi inside the sealed container.

22. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimp seal is made of aluminum and comprises a top crimp member and a bottom washer.

23. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 16~~, wherein the crimp seal is made of steel and comprises a single crimp seal member.

26. (Currently Amended) The improved pharmaceutical container of claim ~~22 or~~ 24, wherein the top crimp member further comprises an insert, said insert being seated in or under the central hole, and further wherein said insert contains a central hole whose diameter is less than the diameter of the central hole in the top crimp member.

27. (Currently Amended) The improved pharmaceutical container of claim 15 ~~or 25~~, wherein said crimp seal comprises a single crimp seal member made of steel with a generally circular surface having a diameter of about 20.75 mm \pm 0.25 mm and a skirt with a height of about 7.00 mm \pm 0.25 mm, and wherein said generally circular surface has a central hole with a diameter of about 5.00 mm \pm 0.25 mm.

28. (Currently Amended) The improved pharmaceutical container of claim ~~15 or~~ 25, further comprising a removable cover which covers the central hole in the top crimp member.

Allowable Subject Matter

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1. Claims 1-4, 6-33, and 38-39 are allowed.
2. The configuration was not found in a prior art search. The following is a listing/
statement of reasons for the indication of allowable subject matter.

The search failed to show or suggest the prior use of:

The configuration/ combination of elements of independent claim 1. An improved pharmaceutical container for containing a pharmaceutical agent which is heated, subjected to increased pressure or radioactive, comprising:

- a. an inlet arm,
- b. an inlet arm support,
- c. a hollow column, and
- d. an outlet arm, and
- e. an outlet arm support, wherein the outlet arm does not protrude into the hollow portion of the column, and a notch is provided in the hollow column at the point where the outlet arm intersects the hollow column.**

3. Dependent claims 2-4, 6-33, and 38-39 are allowable due to dependency upon allowable independent claim 1.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pertinent prior art is closely related art that individually or in combination could be considered grounds for rejection. See references cited for a listing of the pertinent prior art found and the prior art found.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Smyth whose telephone number is 571-270-1746. The examiner can normally be reached on 7:30AM - 5:00PM; Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571-272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 2881

/David A Vanore/

Primary Examiner, Art Unit 2881